



## ROTHWELL, FIGG, ERNST &amp; MANBECK, P.C.

607 14th Street, N.W.  
Suite 800  
Washington, D.C. 20005

Telephone (202) 783-6040  
Facsimile (202) 783-6031  
www.rfem.com  
info@rfem.com

April 29, 2014

Honorable Alison J. Nathan  
United States District Judge  
Thurgood Marshall United States Courthouse  
40 Foley Square, Room 906  
New York, New York 10007

Re: *Braintree Laboratories, Inc. v. Breckenridge Pharmaceutical, Inc.*  
Case No.: 12-cv-6851-AJN

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Dear Judge Nathan:

We represent Defendant Breckenridge Pharmaceutical, Inc. (“Breckenridge”), the successor in interest of Cypress Pharmaceutical, Inc., in the above-referenced action. (*See* D.I. 62.) Pursuant to this Court’s January 17, 2014 order (D.I. 65), we submit this joint letter on behalf of Plaintiff Braintree Laboratories, Inc. (“Braintree”) and Breckenridge to set forth the parties’ recommendation regarding disposition of this case in view of the April 22, 2014 decision of the United States Court of Appeals for the Federal Circuit in *Braintree Laboratories, Inc. v. Novel Laboratories, Inc.*, No. 13-1348 (the “Novel Case”). The Federal Circuit decision is attached as Exhibit A.

The Federal Circuit affirmed-in-part, reversed-in-part, vacated and remanded the decision of the United States District Court for the District of New Jersey in the Novel Case. *See* Exh. A at 2-3. The Federal Circuit affirmed the district court’s construction of the claim term “purgation” and affirmed the district court’s finding that the asserted claims of U.S. Patent No. 6,946,149 (“the ’149 patent”) are not invalid. The Federal Circuit found that the district court erred in its construction of the claim term “clinically significant electrolyte shifts,” vacated the grant of summary judgment of infringement, and remanded “for further factual findings to determine whether the composition covered by Novel’s ANDA product infringes under the new claim construction articulated” in the opinion. *Id.* at 3.

G. Franklin Rothwell  
(1928-2011)

E. Anthony Figg  
Harry F. Manbeck, Jr.  
George R. Repper  
Steven Lieberman  
Joseph A. Hynds  
Martin M. Zoltick  
R. Danny Huntington  
Richard Wydeven  
Sharon L. Davis  
Robert B. Murray  
Jeffrey L. Ihnen  
Martha Cassidy, Ph.D.  
Brian S. Rosenblom  
Jason M. Shapiro  
Brian A. Tolleson  
C. Nichole Gifford  
Joo Mee Kim  
R. Elizabeth Brenner-Leifer  
Nancy J. Linck, Ph.D.

Sharon E. Crane, Ph.D.  
Lisa N. Phillips  
Steven P. Weihrouch  
Robert P. Parker  
Jenny L. Colgate  
Leo M. Loughlin  
Monica Chin Kitts  
Matthew D. Stephens  
Michael V. Battaglia  
Seth E. Cockrum, Ph.D.  
Michael H. Jones  
Rachel M. Echols  
Brett A. Postal  
Erik K. Sivertson\*

Chen Li  
Jeffrey R. Fougere  
Jennifer P. Nock  
Jennifer B. Maisel\*  
Soumya P. Panda\*  
Jason M. Nolan, Ph.D.\*

\*Not a member of the D.C.  
Bar. Practice limited to patent,  
trademark and copyright matters  
and cases in federal courts.

Of Counsel  
William N. Hughet

ROTHWELL, FIGG, ERNST &amp; MANBECK, P.C.

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As this Court is aware, on July 1, 2013, Braintree and Breckenridge entered into a Procedural Stipulation in this matter.<sup>1</sup> That stipulation states, in relevant part:

“[Breckenridge] agrees not to present any defense of non-infringement in this case other than that based on the ‘from about 100 ml to about 500 ml’ limitation present in every asserted claim of the ’149 patent. If the Court denies [Breckenridge’s] Motion, [Breckenridge] stipulates that its proposed generic version of Braintree’s SUPREP described in [Breckenridge’s] ANDA No. 204135... infringes claims 15, 18, 19, 20, and 23 of the ’149 patent; provided, however, that if the Federal Circuit vacates or reverses any portion of the claim construction or infringement determination issued by the District Court in the Novel Case, [Breckenridge] will be permitted to rely upon any final judgment of non-infringement obtained in the Novel Case, whether at the Federal Circuit or upon remand to the District Court.”

(D.I. 41 at ¶ 3.).

Pursuant to this Court’s January 17, 2014 Order (D.I. 65), the parties have met and conferred regarding whether further action in this matter is warranted in light of the Federal Circuit’s decision in the Novel Case. Because the determination of infringement has been remanded to the district court in the Novel Case, the parties respectfully request that this case remain on administrative hold until the completion of proceedings on remand in the Novel Case by final judgment in the U.S. District Court (specifically, the judgment entered after the conclusion of the proceedings on remand from which an appeal may then be taken). Upon completion of such proceedings, the parties will promptly notify this Court and file any appropriate motions. In the event that the parties to the Novel Case settle the action and file a stipulation of dismissal in the U.S. District Court prior to the entry of final judgment in that action, the parties to this action agree to promptly notify this Court and file any appropriate motions. The parties believe that a continuation of the administrative hold in this case favors judicial economy and is in the best interests of the parties; however, the parties reserve the right to seek removal of the administrative hold at an earlier time.

Although the parties agree with respect to the above recommendation as to how this matter should proceed, the parties disagree about the Federal Circuit’s decision and its import to this matter. Therefore, the parties state here their respective positions on that issue:

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<sup>1</sup> The July 1, 2013 Procedural Stipulation was between Braintree and Defendant Cypress Pharmaceutical, Inc. (“Cypress”). (D.I. 41.) On October 15, 2013, Cypress filed a Motion to Substitute a Party, requesting that the Court substitute Breckenridge for Cypress in this matter. (D.I. 61.) In that Motion, Breckenridge agreed to be bound by the July 1, 2013 Procedural Stipulation between Braintree and Cypress. *Id.* On October 16, 2013, this Court issued an Order granting the Motion to Substitute a Party, and ordered that Breckenridge would be bound by the Procedural Stipulation entered by Cypress in this matter. (D.I. 62.)

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**Breckenridge Position:**

Breckenridge notes the issue raised by its motion for summary judgment was not raised by Novel in the district court or on appeal to the Federal Circuit. Nevertheless, Judge Dyk *sua sponte* raised and adopted Breckenridge's arguments that the ANDA product cannot infringe because it does not meet the volume limitation of the claims. *See Exhibit A*, Dyk, J. (dissent). The majority did not address these arguments, and did not indicate whether it disagreed with Judge Dyk's analysis or simply did not address the arguments because they were not raised by the parties in the Novel appeal. Breckenridge reserves the right to present the non-infringement arguments raised by its motion for summary judgment in the event Novel does not prevail in its case on remand.

Breckenridge is further studying the Federal Circuit's ruling and may request a conference to discuss the best way to move forward in this case. However, Breckenridge is not requesting such a conference at this time.

**Braintree Position:**

In its motion for summary judgment, Breckenridge argued noninfringement based on the 'from about 100 ml to about 500 ml' claim limitation. (D.I. 43). In the Novel Case, the district court rejected that same noninfringement defense after the parties fully briefed it in cross-motions for summary judgment on the issue of infringement. *See D.I. 48*, at 24-25; *Braintree v. Novel*, Civil Action No. 3:11-cv-01341 (PGS) (D.N.J.), D.I. 159, at 34-56; D.I. 173, at 28-25; D.I. 176, at 30-42; D.I. 203, at 10-15; D.I. 205, at 13-20; D.I. 261, at 16. Novel did not appeal the district court's rejection of that noninfringement argument (and instead appealed the district court's infringement finding on other grounds), but Judge Dyk raised this issue on appeal *sua sponte*. *See Exhibit A*, at Dyk dissenting opinion. The precedential majority opinion of the Federal Circuit did not adopt Judge Dyk's opinion. *See Exhibit A*, at Prost majority opinion. This shows that the other two judges on the panel considered and rejected the same noninfringement defense that Breckenridge presented in its summary judgment motion. (D.I. 43).

Accordingly, Breckenridge can no longer maintain its sole noninfringement defense, and no further briefing on that subject is warranted. Pursuant to the Procedural Stipulation, all that remains in this case is Breckenridge's potential ability to rely upon any final judgment of noninfringement in the Novel Case. (D.I. 41, ¶ 3).

Respectfully submitted,

Steven Lieberman

cc: All counsel of record

**CERTIFICATE OF SERVICE**

I hereby certify that on April 29, 2014, a true and correct copy of the foregoing **LETTER FROM STEVEN LIEBERMAN TO JUDGE NATHAN** was filed through the Court's Electronic Filing System (ECF), and was served electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

*/s/ Erik van Leeuwen*  
Erik van Leeuwen  
Litigation Operations Manager  
Rothwell, Figg, Ernst & Manbeck, P.C.